REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-9 and 20-30 were pending in this application when last examined.

Claims 5 and 30 were examined on the merits and stand rejected.

Claims 1-4, 6-9 and 20-29 were withdrawn as non-elected subject matter.

Claims 5 and 30 are amended to expedite prosecution and without acquiescence to the correctness of the Office's rejection. Support for the amendments to these claims can be found in the claims as filed and on page 5, lines 1-2, page 11, lines 18-24, and page 16, lines 4-9, of the specification as filed.

Claims 31 and 32 are newly added. Support for newly added claim 31 can be found on page 12, lines 8-11, of the specification as filed. Support for newly added claim 32 can be found on page 11, lines 18-24, and page 12, lines 16-20, of the specification as filed.

No new matter has been added.

II. INFORMATION DISCLOSURE STATEMENT

In item 6 on pages 3-4 of the Office Action, the Office indicated that the IDS filed May 28, 2008 failed to comply because it did not include a concise explanation of the relevancy of each foreign language patent. Applicants respectfully disagree. In particular, a concise explanation of the relevancy of the listed references is set forth in the English translation of the Chinese Office Action attached to the IDS, as well as set forth in item 5 on page 3, of the IDS filed May 28, 2008. As noted in MPEP § 609.04(a)(III), paragraph 2, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the Search Report or Action which indicates the degree of relevance found by the foreign office. Thus, Applicants respectfully request the Examiner to consider this IDS.

III. INDEFINITENESS/35 U.S.C. § 101 REJECTIONS

On page 4 of the Office Action, claim 30 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Office contended that claim 30 was indefinite because it did not recite an active, positive step. Claim 30 is amended to recite an active step and therefore this rejection is overcome.

Also on page 4, claim 30 was rejected under 35 U.S.C. § 101 for lacking any method steps. As noted above, claim 30 is amended and therefore this rejection is moot for reasons which are self-evident.

IV. ANTICIPATION REJECTIONS

On page 5 of the Office Action, claims 5 and 30 were rejected under 35 U.S.C. § 102 as anticipated by MacPhee et al. Further, on pages 5 and 6, claims 5 and 30 were rejected under 35 U.S.C. § 102(b) as anticipated by Spotnitz et al.

Applicants respectfully traverse these rejections as applied to the amended claims for the following reasons.

In particular, Applicants note that the cited references fail to teach or suggest (1) a granule preparation containing freeze-dried fibrin, (2) a granule preparation that is administered by injection or external application, or (3) the surprising and unexpected properties of the claimed invention as taught in the specification.

Characteristics of the Claimed Invention

The claimed invention as defined in amended claim 5 relates to a method of inducing angiogenesis, comprising treating a living body with a granule preparation containing freeze-dried fibrin, wherein the granule preparation is administered by injection or application.

The present inventors found that by treating a living body with a granule preparation containing freeze-dried fibrin, it is possible to obtain excellent and unexpected recovery of blood flow amount as shown in Table 1 on page 29 of the specification. These findings are not obvious to those skilled in the art. Based on these findings, the claimed invention was completed.

MacPhee et al.

Granule Preparation Containing Freeze-Dried Fibrin

MacPhee et al. discloses in column 7, lines 16 to 21, that fibrin gels (0.5-10 mg/ml) implanted subcutaneously in plexiglass chambers induce angiogenesis within 4 days of implantation, compared to empty chambers or chambers filled with sterile culture medium.

Also, MacPhee et al. discloses in column 10, lines 9 to 17, that a method of treating wounded tissue by applying to said wound a fibrin bandage, comprising: (1) an occlusive backing affixed to a layer of dry materials comprising an effective amount of (a) dry fibrinogen, (b) dry thrombin, and, as necessary, (c) effective amounts of calcium and/or Factor XIII to produce a tissue-sealing fibrin clot upon hydration.

Additionally, Mac Phee et al. discloses in column 45, lines 62 to 63, that beneficial effects of fibrin in promoting wound healing and tissue repair have been reported.

Although above-mentioned fibrin bandage of MacPhee et al. comprises fibrinogen and thrombin to produce a tissue-sealing fibrin clot, the cited reference neither discloses nor suggests a granule preparation containing freeze-dried fibrin.

Thus, the invention of claim 5 is quite different from the invention of MacPhee et al.

Further, the claimed invention exhibits excellent activity in inducing angiogenesis by adopting "a granule preparation containing freeze-dried fibrin". In particular, Test Examples 3, 4 and 6 of the present specification are directed towards use of freeze-dried fibrin as prepared on pages 23 and 24 of the specification. For instance, in Test Example 3 on page 27, it is indicated that the blood flow amount in the group-administered freeze-dried fibrin had a remarkably high value compared to the control group. Further, as shown on page 28, of Test Example 4, administration of freeze-dried fibrin caused a remarkable blood flow amount recovery as compared to the control group. Finally, as shown in Test Example 6 on page 31, administration of freeze-dried fibrin resulted in a remarkable improvement in blood flow amount after cutting of the femoral artery as compared to the control.

Applicants note such unexpected and remarkable results for freeze-dried fibrin are neither taught nor suggested by the cited art.

The Granule Preparation is Administered by Injection or Application

MacPhee et al. discloses in column 42, lines 60 to 65, that FG and/or a dressing was placed over the designated wound. MacPhee et al. also discloses in column 55, lines 50 to 55, that each one of 5 animals per group was injected intraperitoneally with 0.5 ml FG (fibrin glue).

However, these administration routes are only for the combination of drugs, i.e. FG (fibrin glue), which is made from the mixing topical fibrinogen complex (TFC), human thrombin and calcium chloride as disclosed in column 10, lines 36 to 38, in MacPhee et al.

On the other hand, the fibrin gels are implanted in MacPhee et al. as mentioned above.

Therefore, the granule preparation which is administered by injection or external application as defined in claim 5 is neither disclosed nor suggested in MacPhee et al.

Spotnitz et al.

Granule Preparation Containing Freeze-Dried Fibrin

Spotnitz et al. discloses in the abstract a method for treating burn wounds comprising a non-adhesive fibrin clot as a stimulator of tissue repair.

Also, Spotnitz et al. discloses on page 7, line 8, that fibrin itself stimulates the healing process.

Additionally, Spotnitz et al. discloses on page 4, lines 24 to 32, and page 7, lines 23 to 24, that the fibrin clots in particulate form are applied to the wound site as a dressing.

However, Spotnitz et al. neither discloses nor suggests a granule preparation containing freeze-dried fibrin.

The invention of claim 5 is quite different from the invention of Spotnitz et al. in requiring a granule preparation containing freeze-dried fibrin.

Further, the claimed invention exhibits excellent and unexpected activity in inducing angiogenesis by adopting "a granule preparation containing freeze-dried fibrin" as shown in Table 1 and Examples 3, 4 and 6 of the specification. Spotnitz et al. fails to teach or suggest that freeze-dried fibrin remarkably and unexpectedly induces high angiogenesis activity.

The Granule Preparation is Administered by Injection or Application

Spotnitz et al. discloses on page 7, lines 23 to 24, that fibrin clots are applied as a dressing. However, this administration route is only for the combination of drugs, i.e. fibrin clots

and silver sulfadiazine as disclosed on page 7, lines 3 to 5, in Spotnitz et al. Therefore, a granule preparation administered by injection or external application as defined in claim 5 is neither disclosed nor suggested in Spotnitz et al.

Thus, Applicants believe that the invention as defined in claim 5 is novel and unobvious over MacPhee et al. and Spotnitz et al.

Amended Claim 30

As mentioned above, MacPhee et al. and Spotnitz et al. neither disclose nor suggest a granule preparation containing freeze-dried fibrin.

MacPhee et al. and Spotnitz et al. also neither disclose nor suggest that the granule preparation is administered by injection or external application.

Finally, neither of the cited references disclose or suggest the surprising and unexpected properties of the claimed invention.

These essential features of claim 30 are neither disclosed nor suggested in any of the prior art references – MacPhee et al. and Spotnitz et al.

Therefore, the claimed invention of claim 30 is novel and unobvious from the prior art references.

New Claims 31 and 32

Applicants note that for the above-noted reasons, claim 5 is not taught or suggested by the cited art. Applicants further note that new claims 31 and 32 are dependent upon amended claim 5 and are therefore also not taught or suggested by the prior art.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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